4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 112

[Docket No. FDA-2011-N-0921]

RIN 0910-AG35

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human

Consumption; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA or we) is correcting the preamble to a proposed rule that published in the <u>Federal Register</u> of January 16, 2013. That proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. FDA proposed these standards as part of our implementation of the FDA Food Safety Modernization Act. The document published with several technical errors, including some errors in cross references, as well as several errors in reference numbers cited throughout the document. This document corrects those errors. We are also placing a corrected copy of the proposed rule in the docket.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA is correcting the preamble to the January 16, 2013 (78 FR 3504), proposed rule entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." The document published with several technical errors, including some errors in cross references, as well as several errors in reference numbers cited throughout the document. This document corrects those errors. In addition, we inadvertently omitted the publication by "Stine et al. (2005)" from section X. References. We also omitted a reference for "Todd et al. (2009)" from section X. References. Therefore, we are correcting the References section to add new Reference 274 for "Stine et al." and new Reference 275 for "Todd et al." We are placing copies of both References 274 and 275 in the docket. We are also placing a corrected copy of the proposed rule in the docket (Ref. 1).

I. Corrections

In FR Doc. 2013-00123, beginning on page 3504, in the <u>Federal Register</u> of Wednesday, January 16, 2013, FDA is making the following corrections:

- 1. On page 3508, in the second column, in the first complete paragraph, in line 5, add the word "uncommon" at the end of the sentence directly in front of "(Ref. 7)."
- 2. On page 3510, in the third column, the heading "B. Produce Safety Action Plan" is corrected to read "C. Produce Safety Action Plan".
- 3. On page 3511, in the first column, the heading "<u>C. Public Hearings</u>" is corrected to read "D. Public Hearings".

- 4. On page 3511, in the second column, the heading "<u>D. Partnerships and</u> Collaborations" is corrected to read "E. Partnerships and Collaborations".
- 5. On page 3513, in the second column, the heading "<u>E. Current Industry Practices</u>" is corrected to read "<u>F. Current Industry Practices</u>".
- 6. On page 3514, in the first column, in the third complete paragraph, in line 3, "section II.D." is corrected to read "section II.E".
- 7. On page 3514, in the first column, the heading "F. 2010 Federal Register Notice and Preliminary Stakeholder Comments" is corrected to read "G. 2010 Federal Register Notice and Preliminary Stakeholder Comments".
- 8. On page 3514, in the third column, beginning in line 26, "V.C" is corrected to read "V.A".
- 9. On page 3516, in the first column, the heading "<u>G. White House Food Safety Working</u> Group" is corrected to read "H. White House Food Safety Working Group".
- 10. On page 3516, in the second column, the heading "<u>H. Other Related Issues</u>" is corrected to read "<u>I. Other Related Issues</u>".
- 11. On page 3519, in the first column, in the first paragraph, in line 10, "II.D.1" is corrected to read "II.E.1".
- 12. On page 3520, in the first column, in line 4, "section X" is corrected to read "section VI".
- 13. On page 3521, in the first column, the heading "<u>F. Intrastate Activities</u>" is corrected to read "<u>E. Intrastate Activities</u>".

- 14. On page 3521, in the third column, the heading "E. Relevance of Section 415 of the FD&C Act to "Farm" Definition and Related Definitions" is corrected to read "F. Relevance of Section 415 of the FD&C Act to "Farm" Definition and Related Definitions".
- 15. On page 3521, in the third column, in the first complete paragraph, the sentence "FDA intends to issue a notice of proposed rulemaking implementing section 418 of the FD&C Act (section 103 of FSMA) in the near future" is corrected to read "Elsewhere in this issue of the Federal Register, FDA is issuing a notice of proposed rulemaking implementing section 418 of the FD&C Act (section 103 of FSMA)".
- 16. On page 3529, in the second column, in the first complete paragraph, in line 42, "(Ref. 35. Ref. 36. Ref. 37)" is corrected to read "(Refs. 2, 92, 142, 165, and 166)".
- 17. On page 3536, in the second column, in the first complete paragraph, in lines 20 and 21, "(Ref. 160. Ref. 161)" is corrected to read "(Refs. 16, and 208)".
- 18. On page 3546, in the third column, in the third complete paragraph, in line 12, "IV.A." is corrected to read "IV.B".
- 19. On page 3553, in the third column, in the first complete paragraph, in line 24, "(Ref. 104)" is corrected to read "(Ref. 198)".
- 20. On page 3556, in the first column, in the second complete paragraph, in lines 23 and 24, "(Ref. 8'Ref. 33'Ref. 18'Ref. 89'Ref. 84)" is corrected to read "(Refs. 10, 20, 26, 48, 50, 96)".
- 21. On page 3556, in the second column, in the first complete paragraph, in line 21, "II.D." is corrected to read "II.E".
- 22. On page 3557, in the first column, in the last line, "(Ref. 93) (Ref. 107)" is corrected to read "(Refs. 26, 107, 234)".

- 23. On page 3557, in the second column, in lines 5 and 6, "(Ref. 95 Ref. 96 Ref. 97 Ref. 98 Ref. 93)" is corrected to read "(Refs. 26, 96, 107, 234)".
- 24. On page 3557, in the third column, in line 9, "(Ref. 89 Ref. 84 Ref. 99)" is corrected to read "(Refs. 43, 44, 46)".
- 25. On page 3557, in the third column, beginning in the last line "(Ref. 44)" is corrected to read "(Ref. 10)".
- 26. On page 3558, in the first column, in the last paragraph, beginning in line 12, "(Ref. 98 Ref. 99 Ref. 100)" is corrected to read "(Refs. 109, 111)".
- 27. On page 3558, in the third column, in the last paragraph, in lines 4 and 5, "(Ref. 89 Ref. 84 Ref. 99)" is corrected to read "(Refs. 43, 44, 46)".
- 28. On page 3559, in the second column, in lines 28 and 29, "(Ref. 89. Ref. 84. Ref. 99)" is corrected to read "(Refs. 44, 46)".
- 29. On page 3559, in the third column, in the first paragraph, in line 22, "(Ref. 89. Ref. 84. Ref. 99)" is corrected to read "(Refs. 44, 46)".
- 30. On page 3560, in the second column, in lines 27, 28, and 29, "(Ref. 107. Ref. 108. Ref. 109. Ref. 110. Ref. 108. Ref. 111. Ref. 112)" is corrected to read "(Refs. 107, 110, 111, 116)".
- 31. On page 3560, in the third column, in the first complete paragraph, in line 19, "(Ref. 109)" is corrected to read "(Ref. 274)".
- 32. On page 3561, in the second column, in the second complete paragraph, in lines 7 and 8, "(Ref. 115, Ref. 116. Ref. 117. Ref. 118)" is corrected to read "(Refs. 116, 117, 118)".
- 33. On page 3562, in the first column, in the second complete paragraph, in lines 14 and 15, "(Ref. 131. Ref. 112)" is corrected to read "(Refs. 116, 131)".

- 34. On page 3562, in the second column, in lines 2 and 3, "(Ref. 132. Ref. 133. Ref. 114. Ref. 123)" is corrected to read "(Refs. 29, 119, 151, 154)".
- 35. On page 3562, in the second column, in the first complete paragraph, in lines 6 and 7, "(Ref. 134. Ref. 135. Ref. 133. Ref. 136. Ref. 137. Ref. 138. Ref. 112)" is corrected to read "(Refs. 119, 134, 136, 137)".
- 36. On page 3562, in the second column, in the first complete paragraph, in line 9, "(Ref. 108) (Ref. 116)" is corrected to read "(Ref. 116)".
- 37. On page 3564, in the first column, in the first complete paragraph, in line 20, "Ref GAPs Guide" is corrected to read "Ref. 10".
- 38. On page 3564, in the second column, in the last paragraph, in line 25, "(Ref. 130)" is corrected to read "(Ref. 274)".
- 39. On page 3564, in the third column, in lines 21 and 22, "(Ref. 131. Ref. 132)" is corrected to read "(Refs. 14, 120, 142)".
- 40. On page 3567, in the third column, in the first complete paragraph, in lines 21 and 22, "(Ref. 132. Ref. 133. Ref. 134. Ref. 135. Ref. 136. Ref. 137. Ref. 108)" is corrected to read "(Refs. 119, 134, 136, 137)".
- 41. On page 3567, in the third column, in the first complete paragraph, in line 42, "(Ref. 133. Ref. 143. Ref. 153. Ref. 131)" is corrected to read "(Refs. 131, 143, 153)".
- 42. On page 3568, in the first column, in the 6th line from the bottom, "(Ref. 133)" is corrected to read "(Ref. 107)".
 - 43. On page 3569, in the second column, in line 1, "(2003)" is corrected to read "(2010)".
- 44. On page 3576, in the third column, in the first complete paragraph, in line 15, "(Ref. 171)" is corrected to read "(Refs. 171, 175)".

- 45. On page 3576, in the third column, in the first complete paragraph, in lines 24 and 25, "(Ref. 171. Ref. 172)" is corrected to read "(Ref. 172)".
- 46. On page 3576, in the third column, in the first complete paragraph, in line 33, "(Ref. 171)" is corrected to read "(Ref. 175)".
- 47. On page 3577, in the third column, in the first paragraph, in lines 22 and 23, "(Ref. 171)" is corrected to read "(Ref. 175)".
- 48. On page 3579, in the first column, in the first paragraph, in lines 34 and 35, "(Ref. 115)" is corrected to read "(Refs. 175, 181)".
- 49. On page 3582, in the first column, in the fifth line from the bottom, "(Ref. 181. Ref. 182. Ref. 183)" is corrected to read "(Refs. 179, 191)".
- 50. On page 3584, in the third column, in the first complete paragraph, in lines 4 and 5, "(a)(1)(a) and (4)(a)" is corrected to read "(a)(1)(i) and (4)(i)".
- 51. On page 3584, in the third column, in the first complete paragraph, in line 13, "(4)(a)" is corrected to read "(4)(i)".
- 52. On page 3586, in the third column, in the first complete paragraph, in lines 10 and 11, "(Ref. 200)" is corrected to read "(Ref. 203)".
- 53. On page 3587, in the second column, in line 2, "(Ref. 199)" is corrected to read "(Ref. 203)".
- 54. On page 3589, in the third column, in the first complete paragraph, in line 39, "(Ref. 226. Ref. 227)" is corrected to read "(Ref. 275)".
- 55. On page 3590, in the second column, in the first complete paragraph, in lines 28 and 29, "(Ref. 182) (Ref. 228)" is corrected to read "(Ref. 228)".

- 56. On page 3591, in the third column, in the first paragraph, in lines 29 and 30, "(Ref. 85. Ref. 94. Ref. 27)" is corrected to read "(Refs. 44, 46)".
- 57. On page 3593, in the first column, in the second complete paragraph, in lines 5 and 6, "(Ref. 85. Ref. 94. Ref. 194)" is corrected to read "(Refs. 44, 46)".
- 58. On page 3593, in the third column, in the first complete paragraph, in lines 5 and 6, "(Ref. 85. Ref. 94. Ref. 194)" is corrected to read "(Refs. 44, 46)".
- 59. On page 3594, in the third column, in the third complete paragraph, in line 17, "(Ref. 38. Ref. 191. Ref. 192. Ref. 193)" is corrected to read "(Refs. 47, 240, 242, 245)".
- 60. On page 3596, in the first column, in the first complete paragraph, in lines 19 and 20, "(Ref. 16. Ref. 196., Ref. 192., Ref. 197)" is corrected to read "(Refs. 16, 241, 242)".
- 61. On page 3596, in the third column, in the first paragraph, in lines 26 and 27, "(Ref. 16. Ref. 18. Ref. 192. Ref. 193)" is corrected to read "(Refs. 16, 18)".
- 62. On page 3596, in the third column, in the first complete paragraph, in line 18, "(Ref. 38. Ref. 18. Ref. 192. Ref. 193)" is corrected to read "(Refs. 18, 47, 240, 245)".
- 63. On page 3597, in the first column, in the second complete paragraph, in lines 10 and 11, "(Ref. 193. Ref. 191. Ref. 38)" is corrected to read "(Refs. 47, 240, 245)".
- 64. On page 3597, in the second column, in line 6, "(Ref. 192. Ref. 201)" is corrected to read "(Refs. 242, 243)".
- 65. On page 3597, in the third column, in the second complete paragraph, in lines 15 and 16, "(Ref. 17. Ref. 252)" is corrected to read "(Ref. 252)".
- 66. On page 3598, in the second column, in line 8, "(Ref. 38. Ref. 191. Ref. 193)" is corrected to read "(Refs. 47, 240, 245)".

- 67. On page 3598, in the second column, in the first complete paragraph, in line 9, "(Ref. 16. Ref. 74)" is corrected to read "(Refs. 16, 50)".
- 68. On page 3598, in the second column, in the first complete paragraph, in lines 20 and 21, "(Ref. 15. Ref. 198. Ref. 209)" is corrected to read "(Refs. 15, 243, 255)".
- 69. On page 3598, in the third column, in the second complete paragraph, in line 8, "(Ref EU OB)" is corrected to read "(Ref. 244)".
- 70. On page 3599, in the second column, in the first paragraph, in line 11, "(Ref. 211. Ref. 212)" is corrected to read "(Refs. 257, 259)".
- 71. On page 3599, in the second column, in the last paragraph, in the 6th line, "(Ref. 213. Ref. 212)" is corrected to read "(Refs. 257, 258)".
- 72. On page 3599, in the third column, in lines 19 and 20, "(Ref. 175. Ref. 212)" is corrected to read "(Refs. 207, 257)".
- 73. On page 3599, in the third column, in the first complete paragraph, in lines 12 and 13, "(Ref. 175. Ref. 211)" is corrected to read "(Refs. 254, 258, 259)".
- 74. On page 3600, in the first column, in line 27, "(Ref. 175. Ref. 211)" is corrected to read "(Refs. 207, 259)".
- 75. On page 3600, in the first column, in the first complete paragraph, in line 7, "(Ref. 175. Ref. 211) (Ref. 257)" is corrected to read "(Ref. 257)".
- 76. On page 3600, in the third column, in the second complete paragraph, in lines 28 and 29, "(Ref. 180. Ref. 221. Ref. 219)" is corrected to read "(Refs. 207, 257, 259)".
- 77. On page 3601, in the first column, in the first paragraph, in lines 25 and 26, "(Ref. 15. Ref. 206. Ref. 201. Ref. 203)" is corrected to read "(Refs. 15, 240, 242, 245)".

- 78. On page 3601, in the first column, in the first complete paragraph, in lines 8 and 9, "(Ref. 15. Ref. 223. Ref. 224)" is corrected to read "(Refs. 15, 255)".
- 79. On page 3604, in the third column, in the first complete paragraph, in line 33, "(Ref. 44)" is corrected to read "(Ref. 262)".
- 80. On page 3608, in the third column, in the first complete paragraph, in line 4, "II.D." is corrected to read "II.E".
- 81. On page 3619, in the second column, in lines 3 and 4, "(Ref. 268. Ref. 269. Ref. 270. Ref. 271. Ref. 272. Ref. 267)" is corrected to read ("Refs. 267, 268, 269, 270, 271)".
- 82. On page 3625, in the first column, in Reference 156, the year "1988" is corrected to read "1998".
- 83. On page 3628, in the first column, Reference 274 is added in numerical order to read: "274. Stine, S. W., Song, I., Choi, C. Y., Gerba, C. P., "Application of Microbial Risk Assessment to the Development of Standards for Enteric Pathogens in Water Used to Irrigate Fresh Produce." Journal of Food Protection, 68(5): 913-918, 2005."
- 84. On page 3628, in the first column, Reference 275 is added in numerical order to read: "275. Todd E. C. D., Greig J. D., Bartleson C. A. et al., Outbreaks Where Food Workers Have Been Implicated in the Spread of Foodborne Disease. Part 6. Transmission and Survival of Pathogens in the Food Processing and Preparation Environment. <u>Journal of Food Protection</u>, 72(1): 202-219, 2009."

II. Reference

The following reference has been placed on display in the Division of Dockets

Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4

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p.m., Monday through Friday. This reference is also available electronically at http://www.regulations.gov.

1. FDA, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for

Human Consumption; Proposed Rule" (corrected version), 2013.

Dated: March 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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